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RHÔNE-POULENC INC.
CN 7500, CRANBURY, NJ 08512-7500
TELEPHONE: (609) 395-8300

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8E HQ-92-12091
INIT
88920010329

September 4, 1992

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED
P 713 002 185**

Document Processing Center (TS-790)
Attn: Section 8(e) Coordinator (CAP Agreement)
Office of Toxic Substances
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance
Audit Program

CAP ID NO.: 8ECAP - 0004

RP CAP REPORT NO.: RPS - 0173

Dear Sir/Madam:

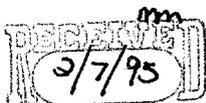
On behalf of Rhône-Poulenc Inc. (RPI, CN5266, Princeton, NJ 08543-5266) and its subsidiaries, the attached report is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA (8ECAP - 0004).

The enclosed report provides information on the following chemical substance:

Product Name:	Alacsan 7LUF (Currently Cycloton 7 LUF)	
Identity:	Oleyl dimethyl benzyl amonium chloride	55%
	Water	45%

CAS Registry No.: 37139-99-4

CAS Registry Name: Benzenemethanaminium,N,N-dimethyl-N-9-Octadecenyl-chloride,(Z)-



The title of the enclosed report is:

Eye Irritation Test in Rabbits

The following is a summary of the adverse effects observed in this report.

The test material was found to be a severe ocular irritant. Corneal, iridial, and conjunctival irritation was observed in all animals throughout the 7-day observation period. No evidence of reversibility was observed. Rinsing the eye dramatically reduced the severity of the irritation. (pH = slightly acidic)

RPI does not claim any portion of the information in this submission to be confidential business information (CBI).

RPI has not previously submitted any TSCA Section 8(e) notices or premanufacture notification on the subject chemical substance.

RPI has submitted four additional studies on this material under the CAP Agreement; see RP CAP Report Nos. RPS - 0068, RPS - 0090, RPS - 0091, and RPS - 0092.

In total, RPI is submitting three copies of the enclosed report and this cover letter: an original and two copies.

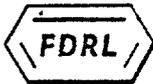
Further questions regarding this submission may be directed to Dr. Glenn S. Simon, Director of Toxicology at (919)549-2222 (Rhône-Poulenc, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709).

Sincerely,



Charles E. Moyer, Jr., Ph.D.
Director, Product Safety
(609)860-3589

CEMjr/mm
Enclosures



FOOD AND DRUG
Research LABORATORIES, INC.

WAVERLY RESEARCH CENTER
Route 17C
P. O. Box 107
Waverly, New York 14892
(607) 565-2931

R E P O R T

Submitted to: Alcolac, Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

Date: May 14, 1977

Laboratory No. 5453

Sample: Clear viscous liquid.

Marking: ALACSAN 7LUF QUATERNARY AMMONIUM COMPOUND 700701;
Control No. 4905

Examination Requested: Eye Irritation Test in Rabbits

Purpose: To determine the effects of the test material to the rabbit eye.

Procedure: The acute eye irritation test was determined on 9 young adult albino rabbits, selected from healthy, acclimated animals. The test material at the level of 0.1 ml or 0.1 g was applied to the right eye of each animal.

The method employed was patterned after the procedure described in 16 CFR 1500.42.

The test procedure was modified as follows:

Group I: Six rabbits; eyes unwashed following the instillation of the test material.

Group II: Three rabbits; eyes washed 4 seconds following instillation of the test material.

All eyes were observed and ocular reaction recorded at 24, 48, and 72 hours after instillation of the test material. They were observed again after 7 days.

CAP ID No. 2-112-BAK-0031
Reviewed for Sec. 8 (e)
Compliance Program
On 5/29/91 By BAS

Table 1

Laboratory No. 5453_b
 Individual Rabbit Eye Irritation Scores*
 (ALACSAN 7LUF QUATERNARY AMMONIUM COMPOUND No Washout (Group I)

Rabbit No. & Sex	Item	700701; Control No. 4905 Tissue	Reading			Day
			24	48	72	
1	A	Cornea Opacity	4	4	4	4
	B	Cornea Area	4	4	4	4
		(1) Cornea Total = (AxB) x 5	80	80	80	80
	C	Iris	2	2	2	2
		(2) Iris Total = (C) x 5	10	10	10	10
	D	Conjunctiva Redness	2	2	2	2
	E	Conjunctiva Chemosis	4	4	4	4
	F	Conjunctiva Discharge	3	3	3	3
		(3) Conjunctiva Total = (D+E+F) x 2	18	18	18	18
	Totals Added = (1+2+3)	108	108	108	108	
2	A	Cornea Opacity	4	4	4	4
	B	Cornea Area	4	4	4	4
		(1) Cornea Total = (AxB) x 5	80	80	80	80
	C	Iris	2	2	2	2
		(2) Iris Total = (C) x 5	10	10	10	10
	D	Conjunctiva Redness	2	2	2	2
	E	Conjunctiva Chemosis	4	4	4	4
	F	Conjunctiva Discharge	3	3	3	3
		(3) Conjunctiva Total = (D+E+F) x 2	18	18	18	18
	Totals Added = (1+2+3)	108	108	108	108	
3	A	Cornea Opacity	4	4	4	4
	B	Cornea Area	4	4	4	4
		(1) Cornea Total = (AxB) x 5	80	80	80	80
	C	Iris	2	2	2	2
		(2) Iris Total = (C) x 5	10	10	10	10
	D	Conjunctiva Redness	2	2	2	2
	E	Conjunctiva Chemosis	4	4	4	4
	F	Conjunctiva Discharge	3	3	3	3
		(3) Conjunctiva Total = (D+E+F) x 2	18	18	18	18
	Totals Added = (1+2+3)	108	108	108	108	

*See attached sheet for "Scale for Scoring Ocular Lesions"

Table 1

Laboratory No.5453_b

Individual Rabbit Eye Irritation Scores*

(ALACSAN 7LUF QUATERNARY AMMONIUM COMPOUND: No Washout (Group I)

Rabbit No. & Sex	Item	700701; Control No. 4905) Tissue	Reading			Day
			Hours 24	48	72	
4	A	Cornea Opacity	4	4	4	4
	B	Cornea Area	4	4	4	4
		(1) Cornea Total = (AxB) x 5	80	80	80	80
	C	Iris	2	2	2	2
		(2) Iris Total = (C) x 5	10	10	10	10
	D	Conjunctiva Redness	2	2	2	2
	E	Conjunctiva Chemosis	4	4	4	4
	F	Conjunctiva Discharge	3	3	3	3
		(3) Conjunctiva Total = (D+E+F) x 2	18	18	18	18
	Totals Added = (1+2+3)	108	108	108	108	
5	A	Cornea Opacity	4	4	4	4
	B	Cornea Area	4	4	4	4
		(1) Cornea Total = (AxB) x 5	80	80	80	80
	C	Iris	2	2	2	2
		(2) Iris Total = (C) x 5	10	10	10	10
	D	Conjunctiva Redness	2	3	3	2
	E	Conjunctiva Chemosis	4	4	4	4
	F	Conjunctiva Discharge	3	3	3	3
		(3) Conjunctiva Total = (D+E+F) x 2	18	20	20	18
	Totals Added = (1+2+3)	108	110	110	108	
6	A	Cornea Opacity	4	4	4	4
	B	Cornea Area	4	4	4	4
		(1) Cornea Total = (AxB) x 5	80	80	80	80
	C	Iris	2	2	2	2
		(2) Iris Total = (C) x 5	10	10	10	10
	D	Conjunctiva Redness	2	2	2	2
	E	Conjunctiva Chemosis	4	4	4	4
	F	Conjunctiva Discharge	3	3	3	3
		(3) Conjunctiva Total = (D+E+F) x 2	18	18	18	18
	Totals Added = (1+2+3)	108	108	108	108	



Individual Rabbit Eye Irritation Scores*

(ALACSAN 7LUF QUATERNARY AMMONIUM COMPOUND 4-Sec. Washout (Group

700701; Control No. 4905)

Reading

Rabbit
No. &
Sex

Item

Tissue

---Hours---

24 48 72

Day

7

1

A	Cornea	Opacity	0	0	0			0
B	Cornea	Area	0	0	0			0
	(1) Cornea Total = (AxB) x 5		0	0	0			0
C	Iris		1	0	0			0
	(2) Iris Total = (C) x 5		5	0	0			0
D	Conjunctiva	Redness	2	1	1			0
E	Conjunctiva	Chemosis	2	1	1			0
F	Conjunctiva	Discharge	3	2	1			1
	(3) Conjunctiva Total = (D+E+F) x 2		14	8	6			2
	Totals Added = (1+2+3)		19	8	6			2

2

A	Cornea	Opacity	0	0	0			0
B	Cornea	Area	0	0	0			0
	(1) Cornea Total = (AxB) x 5		0	0	0			0
C	Iris		0	0	0			0
	(2) Iris Total = (C) x 5		0	0	0			0
D	Conjunctiva	Redness	1	1	1			0
E	Conjunctiva	Chemosis	1	0	0			0
F	Conjunctiva	Discharge	2	0	0			0
	(3) Conjunctiva Total = (D+E+F) x 2		8	2	2			0
	Totals Added = (1+2+3)		8	2	2			0

3

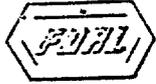
A	Cornea	Opacity	0	0	0			0
B	Cornea	Area	0	0	0			0
	(1) Cornea Total = (AxB) x 5		0	0	0			0
C	Iris		0	0	0			0
	(2) Iris Total = (C) x 5		0	0	0			0
D	Conjunctiva	Redness	1	1	1			0
E	Conjunctiva	Chemosis	1	1	0			0
F	Conjunctiva	Discharge	1	1	0			0
	(3) Conjunctiva Total = (D+E+F) x 2		6	6	2			0
	Totals Added = (1+2+3)		6	6	2			0

*See attached sheet for "Scale for Scoring Ocular Lesions"

Table

Scale for Scoring Ocular Lesions

Codes*

(1) Cornea

(A) Opacity-degree of density (area most dense taken for reading)

No Opacity

Scattered or diffuse area, details of iris clearly visible

Easily discernible translucent areas, details of iris slightly obscured

Opalescent areas, no details of iris visible, size of pupil barely discernible

Opaque, iris invisible

(B) Area of cornea involved

One quarter (or less) but not zero

Greater than one quarter, but less than half

Greater than half, but less than three quarters

Greater than three quarters, up to whole area

A X B X 5

Total Maximum = 80

(2) Iris

(A) Values

Normal

Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combination of any thereof) iris still reacting to light (sluggish reaction is positive)

No reaction to light, hemorrhage, gross destruction (any or all of these)

A X 5

Total Maximum = 10

(3) Conjunctivae

(A) Redness (refers to palpebral and bulbar conjunctivae excluding cornea and iris)

Vessels normal

Vessels definitely injected above normal

More diffuse, deeper crimson red, individual vessels not easily discernible

Diffuse beefy red

(B) Chemosis

No swelling

Any swelling above normal (includes nictitating membrane)

Obvious swelling with partial eversion of lids

Swelling with lids about half closed

Swelling with lids about half closed to completely closed

(C) Discharge

No discharge

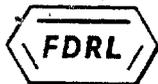
Any amount different from normal (does not include small amounts observed in inner canthus of normal animals)

Discharge with moistening of the lids and hairs just adjacent to lids

Discharge with moistening of the lids and hairs, and considerable area around the eye

Score (A + B + C) X 2

Total Maximum = 20



FOOD AND DRUG
Research LABORATORIES, INC.

WAVERLY RESEARCH CENTER
Route 17C
P. O. Box 107
Waverly, New York 14892
(607) 565-2931

Results: See Table for eye irritation scores of rabbit eyes with no washout after instillation of the test material (Group I).

Table 2 presents the ocular reactions of rabbit eyes washed 4 seconds after instillation of the test material (Group II).

Group I: Corneal, iridial, and conjunctival effects were observed in all six animals. These effects persisted throughout the 7-day observation period.

Group II: Iridial effects was observed in one animal. Conjunctival effects were observed in all three. Iridial effects cleared in one animal, and conjunctival effects cleared in two animals during the 7-day observation period.

Conclusion: On the basis of the data presented herein, the following is concluded for the test material identified above:

Group I: It is a severe irritant to the rabbit eye when not followed by a washout after instillation of the test material.

Group II: It is a mild transient irritant to the rabbit eye when followed by a washout 4 seconds after instillation of the test material.

Jean Griffiths
Jean Griffiths,
Study Director

John G. Babish
John G. Babish, Ph.D.
Staff Toxicologist
Waverly Research Center



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Charles E. Moyer, Jr., Ph.D.
Director, Product Safety
Rhône-Poulenc Inc.
CN 7500
Cranberry, New Jersey 08512-7500

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 06 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12091A



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Triage of 8(e) Submissions

Date sent to triage: 12/8/95

NON-CAP

CAP

Submission number: 12091A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: 0 1 2 pages 1, 2 pages 1, 2, tab

Notes:

Contractor reviewer: LPS Date: 3/10/95

CECATS DATA: Submission # 8EHQ 0992-12091 SEQ. A
 TYPE: INT SUPP FLWP
 SUBMITTER NAME: Phone - Polenc Inc.

INFORMATION REQUESTED: FLWP DATE: _____
 0501 NO INFO REQUESTED
 0502 INFO REQUESTED (TECH)
 0503 INFO REQUESTED (VOL ACTIONS)
 0504 INFO REQUESTED (REPORTING RATIONAL/F)
 DISPOSITION:
 0639 REFER TO CHEMICAL SCREENING
 0678 CAP NOTICE

VOLUNTARY ACTIONS:
 0401 NO ACTION REPORTED
 0402 STUDIES PLANNED/IN PROGRESS
 0403 NOTIFICATION OF WORK REQUESTED
 0404 LABEL/MSDS (CHANGE)
 0405 PROCESS/MSDS (CHANGE)
 0406 APPAUSE DISCONTINUED
 0407 PRODUCTION DISCONTINUED
 0408 CONFIDENTIAL

SUB DATE: 09/04/92 OIS DATE: 09/22/92 CSRAD DATE: 02/07/95
 CAS# 37139-99-4

CHEMICAL NAME: Alcason TLUF -> none
Cyclohex 7 LUF -> none

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPICLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECOAQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCUREL/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQUEST DELAY	01 02 04	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROD/COMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0299 OTHER	01 02 04
0211 CHR. TOX (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
0212 ACUTE TOX (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0229 METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0240 METAB/PHARMACO (HUMAN)	01 02 04		

TRADE DATA: NON-CBI INVENTORY
 YES
 NO
 CAS SR: IN TRIMINI REPR

ONGOING REVIEW: YES (DROP/REFER)
 NO (CONTINUE)

SPECIES: RAT

TOXICOLOGICAL CONCERN: LOW
 MED HIGH Eye Irr

USE: _____ PRODUCTION: _____

UNRECD

12091A

H

Eye irritation in the rabbit is of high concern. Application of 0.1 mL or 100 mg to one eye of six albino rabbits resulted in severe eye irritation within 24 hours, which persisted during the 7-day observation period. Effects in all animals included opaque corneas, no reaction to light and destruction of the iris, and redness, swelling, and discharge of the conjunctiva. Washing the eyes immediately after application resulted in mild irritation which disappeared by day 7.